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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,745	04/13/2001	Joseph Roberts	78728/106	2894
22428	7590	10/13/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/833,745

Applicant(s)

ROBERTS ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-20 and 28-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-12, 28, 29, 31, 32, 34 and 35 is/are allowed.
- 6) ☒ Claim(s) 13-20, 30 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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After reading applicants remarks regarding entering amended Figure 8 in the instant the examiner will allow it to be entered. It is deemed that the specification adequately describes the figure. Applicants are strongly urged to incorporate priority applications into new applications as that would eliminate this problem.

It is noted that the figures filed 6/3/03 are apparently informal figures as they contain crossovers. At least the instant figures should be submitted as formal drawings.

Claims 30 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 and 33 are incorrect and therefore confusing in the recitation of "Streptomyces coelicolor..Mus musculus" and "Rhizobium meiloti, and Halobacterium", which should be "Streptomyces coelicolor..Mus musculus" and "Rhizobium meiloti, and Halobacterium".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants argue that claim 13 is an original claim and that original claims have "a strong presumption" of enablement in the specification. It is pointed out that original claim 13 is drawn to "[a] method for treating disease" not "reducing toxicity in normal cells from chemotherapeutic agents" and secondly the "strong presumption" does not preclude a review of the enablement. The examiner has considered paragraph 78 and the two references referenced in the first paragraph on page 13 of applicants' amendment and has concluded that applicants had possession of claim 13 limited to chemotherapeutic agents but not retroviral vectors. Applicants do not discuss what effect adding retroviral vectors would have and do not point to anywhere in the specification that this is discussed. There is no discussion of this in paragraph 78 nor apparently in the two references.

Applicants further argue with respect to claim 16 that "it was well-known...that histidine ammonia lyase converts histidine into...t-UA...[, that] irradiation...causes the photoisomerization of t-UA to...c-UA...[and that] "c-UA plays a role in UVB-induced immunosuppressive mediators". They further urge that "applicants explained that administering a therapeutically effective amount of...histidine ammonia lyase activity generates t-UA *in vivo* and that irradiating the patient causes the photoisomerization of t-UA to c-UA, which exhibits immunosuppressive properties", with paragraph 82 being referenced. The instant paragraph states that "small molecules like urocanic acid are rapidly cleared from the circulation, thereby limiting their use as effective immunosuppressors...[but that] PEGylkated HAL has a long circulatory half-life ...[and] can be used to generate circulating urocanic acid for prolonged

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periods of time". Claims 16-20 do not contain this limitation (PEGylated HAL) which would apparently make HAL effective in delivering an immunosuppressant.

Therefore it is maintained that applicants did not have possession of the invention as claimed.

Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

The instant enablement rejection of the instant claims is repeated for essentially the reasons given for the written description rejection *supra*. The previous rejection of claims 7-12 is dropped after careful consideration of applicants remarks and the cited references. It is maintained that one of ordinary skill in the art would not be taught how to make and/or use the claimed invention.

Claims 7-12 and 28-29, 31-32 and 34-35 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final


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action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
October 5, 2004